

Clinical Trial Demographic Scorecard

Drug	
Tradename	Tryptyr
Generic Name	acoltremon
Company	Alcon Labs
Date of FDA Approval	May 28, 2025
Indication	To treat the signs and symptoms of dry eye disease

OVERALL GRADE

B



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	11.2%	50	Increased	B



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	74.8%	350	Increased	A



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	13.9%	70	Similar	B
Asian	6.3%	8.5%	40	Increased	B



Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	11.8%	47	Increased	D

References: Phase 3 pivotal trials: COMET-2 [NCT-05285644] and COMET-3 [NCT-05360966];
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/217370Orig1s000IntegratedR.pdf pgs 21,22, 32;
doi:10.1001/jamaophthalmol.2022.4394; doi: 10.1016/j.ajo.2011.02.026;
<https://www.ajo.com/action/showPdf?pii=S0002-9394%2817%2930290-8>; DOI: 10.1016/s0002-9394(03)00218-6; No PMR/PMC

Clinical Trial Demographic Scorecard

Drug	
Tradename	Emrelis
Generic Name	telisotuzumab vedotin-tllv
Company	Abbvie
Date of FDA Approval	May 14, 2025
Indication	To treat locally advanced or metastatic, non-squamous non-small cell lung cancer (NSCLC) with high c-Met protein overexpression after prior systemic therapy

OVERALL GRADE



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	50.0%	84	Increased	B



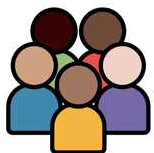
Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	30.4%	51	Similar	C



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	1.8%	3	Similar	D
Asian	6.3%	32.7%	55	Decreased	A



Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	0.6%	1	Decreased	C

References: Phase 3 pivotal trial Luminosity M14-239 ;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/761384Orig1s000MultidisciplineR.pdf pgs 96-97;
doi: 10.1177/17588359241279715; <https://doi.org/10.1186/s12885-024-12126-8>;
<https://www.ncbi.nlm.nih.gov/books/NBK519578/#:~:text=Lung%20adenocarcinoma%20is%20the%20most,p>
atients%20affected%20by%20lung%20adenocarcinoma.; No PMR/PMC

Clinical Trial Demographic Scorecard

Drug	
Tradename	Avmapki Fakzynja Co-Pack
Generic Name	avutometinib and defactinib
Company	VERASTEM INC
Date of FDA Approval	May 8, 2025
Indication	To treat KRAS-mutated recurrent low-grade serous ovarian cancer (LGSOC) after prior systemic therapy (orphan)

OVERALL GRADE

C



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	28.7%	33	Increased	B



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	100%	115	Increased	NA



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	4.3%	5	Decreased	C
Asian	6.3%	3.5%	4	Decreased	C



Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	2.2%	3	Similar	D

References: Phase 3 pivotal trial RAMP-201;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/219616Orig1s000MultidisciplineR.pdf pgs 173,175; <https://seer.cancer.gov/statfacts/html/ovary.html>;
<https://gis.cdc.gov/Cancer/USCS/#/explore/incidence>; No PMR/PMC

Clinical Trial Demographic Scorecard

Drug	
Tradename	Imaavy
Generic Name	nipocalimab-aahu
Company	JANSSEN BIOTECH
Date of FDA Approval	April 29, 2025
Indication	To treat generalized myasthenia gravis (orphan)

OVERALL GRADE

C



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	24.2%	18	Increased	C



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	60.1%	50	Increased	C



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	1.3%	1	Increased	F
Asian	6.3%	32.0%	24	Similar	B



Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	7.8%	8	Decreased	C

References: Phase 3 pivotal trial 011;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/761430Orig1s000IntegratedR.pdf pgs 47-48;
<https://doi.org/10.1212/WNL.0000000000202945>; doi: 10.3389/fneur.2024.1339167;
doi: 10.3390/jcm10112235; <https://www.rarediseaseadvisor.com/disease-info-pages/myasthenia-gravisepidemiology/>;
<https://rarediseases.org/rare-diseases/myasthenia-gravis/#affected>; No PMR/PMC

Clinical Trial Demographic Scorecard

Drug	
Tradename	penpulimab-kcqx
Generic Name	penpulimab-kcqx
Company	AKESO BIOPHARMA
Date of FDA Approval	April 23, 2025
Indication	To treat adults with non-keratinizing nasopharyngeal carcinoma (orphan)



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	5.0%	16	Similar	D



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	20.4%	56	Decreased	B



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	0.2%	0	Similar	D
Asian	6.3%	98.3%	270	Increased	B



Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	1.0%	2	Decreased	C

OVERALL GRADE

C

References: Phase 3 pivotal trials AK105-304, AK105-202;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/761258Orig1s000MultidisciplineR.pdf pgs 95,99,131, 220; PMID: 37227924 DOI: 10.34067/KID.0000000000000165; doi: 10.1016/j.ekir.2023.02.1086
PMCID: PMC10166729; PMID: 37180506; DOI: 10.1159/000541869; PMID: 35757475;
doi:10.1001/archotol.132.10.1035 PMC for demographic subgroups that are reflective of the U.S. patient population

Clinical Trial Demographic Scorecard

Drug	
Tradename	Vanrafia
Generic Name	atrasentan
Company	Novartis
Date of FDA Approval	April 2, 2025
Indication	To reduce proteinuria in adults with primary IgA nephropathy at risk of rapid disease progression



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	6.3%	11	Decreased	C



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	41.1%	54	Decreased	A



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	1.9%	4	Decreased	C
Asian	6.3%	57.0%	75	Increased	B



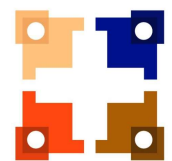
Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	20.7%	32	Similar	B

OVERALL GRADE

B

References: Phase 3 pivotal trial ALIGN;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/219208Orig1s000IntegratedR.pdf pgs 36-37;
PMID: 37227924 DOI: 10.34067/KID.0000000000000165; doi: 10.1016/j.ekir.2023.02.1086 PMCID:
PMC10166729; PMID: 37180506; DOI: 10.1159/000541869; No PMR/PMC



Clinical Trial Demographic Scorecard

Drug	
Tradename	Qfitlia
Generic Name	fitusiran
Company	Genzyme
Date of FDA Approval	March 28, 2025
Indication	To prevent or reduce the frequency of bleeding episodes in hemophilia A or B (orphan)



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	1.0%	3	Decreased	C



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	NA	NA	NA	NA



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	1.1%	3	Decreased	C
Asian	6.3%	62.1%	169	Decreased	A



Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	4.0%	5	Similar	D

OVERALL GRADE

C

References: Phase 3 pivotal trials ATLAS-INH (EFC14768), ATLAS-A/B (EFC14769); DOI: 10.1111/hae.13998 ; DOI: 10.1182/asheducation-2010.1.191; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/219019Orig1s000IntegratedR.pdf pgs. 49, 53, 62, 100, 252 ; No PMR/PMC

Clinical Trial Demographic Scorecard

Drug	
Tradename	Blujepa
Generic Name	gepotidacin
Company	GSK
Date of FDA Approval	March 25, 2025
Indication	To treat uncomplicated urinary tract infections



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	23.3%	353	Increased	A



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	100%	1,572	Increased	A



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	6.9%	114	Similar	C
Asian	6.3%	5.1%	74	Similar	B



Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	32.7%	524	Similar	A

OVERALL GRADE

A

References: Phase 3 pivotal trials EAGLE-2, EAGLE-3;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/218230Orig1s000IntegratedR.pdf pg 23, 50;
[doi: 10.1177/1756287219832172](https://doi.org/10.1177/1756287219832172); <https://www.ncbi.nlm.nih.gov/books/NBK470195/>; No PMR/PMC

Clinical Trial Demographic Scorecard

Drug	
Tradename	Romvimza
Generic Name	vimseltinib
Company	DECIPHERA PHARMS
Date of FDA Approval	February 14, 2025
Indication	To treat symptomatic tenosynovial giant cell tumor

OVERALL GRADE

D



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	9.8%	5	Decreased	C



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	59.3%	46	Increased	C



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	3.3%	4	Unknown	D
Asian	6.3%	4.1%	1	Increased	D



Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	3.3%	3	Unknown	D

References: Pivotal Phase 3 trial DCC-3014-03-001 MOTION;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/219304Orig1s000MultidisciplineR.pdf pg 132;
<https://rarediseases.org/rare-diseases/tenosynovial-giant-cell-tumor/#affected>; DOI: 10.1016/j.ctrv.2022.102491; DOI: 10.1038/srep36332; No PMR/PMC

Clinical Trial Demographic Scorecard

Drug	
Tradename	Gomekli
Generic Name	mirdametinib
Company	SPRINGWORKS
Date of FDA Approval	February 11, 2025
Indication	To treat neurofibromatosis type 1 (orphan)



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	1.8%	2	Decreased	C



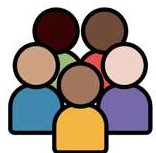
Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	58.8%	67	Similar	B



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	14.0%	16	Similar	C
Asian	6.3%	3.5%	4	Similar	D



Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	7.9%	9	Similar	D

OVERALL GRADE



References: Pivotal Phase 3 trial MEK-NF-201 ReNeu ;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/219379Orig1s000,219389Orig1s000MultidisciplineR.pdf pg 150;
<https://rarediseases.org/rare-diseases/neurofibromatosis-type-1-nf1/#affected>; DOI: 10.3928/01913913-20190321-02;
<https://nfpittsburgh.org/whatisnf/facts-statistics/>; No PMR/PMC

Clinical Trial Demographic Scorecard

Drug	
Tradename	Journavx
Generic Name	suzetrigine
Company	Vertex
Date of FDA Approval	January 30, 2025
Indication	To treat moderate to severe acute pain



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	4.8%	47	Increased	D



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	91.7%	803	Increased	A



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	25.5%	239	Increased	B
Asian	6.3%	1.8%	16	Decreased	C



Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	34.0%	281	Increased	B

OVERALL GRADE

B

References: Pivotal Phase 3 trials VX22-548-104, VX22-548-105 ;
 https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/219209Orig1s000IntegratedR.pdf pgs 26,27,33; doi: 10.7861/clinmed.22.4.ac-p; PMID: 26526704; <https://doi.org/10.1111/pme.12528>; PMID: 35260338; PMID: 25422152; No PMR/PMC

Clinical Trial Demographic Scorecard

Drug	
Tradename	Grafapex
Generic Name	treosulfan
Company	MEDEXUS
Date of FDA Approval	January 21, 2025
Indication	For use in allogeneic hematopoietic stem cell transplantation for AML and MDS (orphan)

OVERALL GRADE



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	26.0%	76	Increased	B



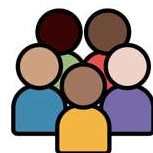
Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	39.1%	109	Decreased	A



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	NR	NR	Decreased	C
Asian	6.3%	NR	NR	Decreased	C



Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	NR	NR	Decreased	C

References: Pivotal Phase 3 trial MC-FludT.14/L Trial II;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/214759Orig1s000MultidisciplineR.pdf pg 37;
<https://seer.cancer.gov/statfacts/html/amyl.html>; https://seer.cancer.gov/statistics-network/explorer/application.html?site=409&data_type=1&graph_type=10&compareBy=sex&chk_sex_3=3&chk_sex_2=2&series=9&race=8&age_range=1&hdn_stage=101&advopt_precision=1&advopt_show_ci=on&hdn_view=0; PMC for race and ethnicity

Clinical Trial Demographic Scorecard

Drug	
Tradename	Datroway
Generic Name	datopotamab deruxtecan-dlnk
Company	DAIICHI SANKYO INC
Date of FDA Approval	January 17, 2025
Indication	To treat unresectable or metastatic, HR-positive, HER2-negative breast cancer



Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	22.3%	91	Increased	B



Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	98.8%	360	Increased	NA



Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	1.5%	4	Decreased	C
Asian	6.3%	40.7%	146	Decreased	A



Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	11.3%	40	Decreased	B

OVERALL GRADE

B

References: Pivotal Phase 3 trial TROPION-Breast01;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/761394Orig1s000MultidisciplineR.pdf pgs 135-6;
<https://seer.cancer.gov/statfacts/html/breast-subtypes.html>; PMID: 36895447; PMC for race and ethnicity